

REMARKS

This paper responds to the Office Action of March 2, 2011 in which the Examiner rejected claim 1 under 35 U.S.C. § 112 and rejected claims 1-5, 7-11, 12, 13-15, 16, 17-19 and 22-25 under 35 U.S.C. § 103(a).

In response, claims 1, 2, 3, 7, 8, 12, 13, 16, 18, 19, 23 and 24 have been amended and claim 17 has been cancelled. No new matter has been introduced.

Reconsideration and allowance are requested.

Interview Summary

The interview between Bridget Hayden and Examiner Mendez on May 25, 2011 is appreciated. During the interview, potential claim amendments, i.e., those of this paper, were discussed. While no formal agreement was reached, it is believed that upon entry of this paper all outstanding issues will be resolved and the present application will be in condition for allowance. If the Examiner believes further discussion or an Examiner's amendment is necessary for allowance, he is invited to contact the undersigned or Bridget Hayden at (612) 492-6867.

Rejections under 35 U.S.C. § 103(a)

Claim 1 was rejected under 35 U.S.C. § 112, second paragraph, as lacking antecedent basis for the claim limitation "the center-point of the bending beams." The rejection is traversed because "Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation 'the outer surface of said sphere' would not require an antecedent recitation that the sphere has an outer surface." *MPEP* 2173.05. Similarly, a bending beam would inherently include a center-point. However, to advance prosecution, independent claim 1 has been amended to recite: "the notched cam being fixed to a center-point of the bending beam."

Reconsideration and withdrawal of the § 112, second paragraph rejection are requested.

Rejections under 35 U.S.C. § 103(a)

Claims 1-5, 7-11, 12, 13-15, 16, 17-19 and 22-25 were rejected under 35 U.S.C. § 103(a) as unpatentable over US Patent 2,823,743 (Ashkenaz) in view of US Patent 6,575,955 (Azzolini), US Patent 5,445,631 (Uchida), US Patent 4,936,841 (Aoki) or US Patent 5,137,524 (Lynn). The § 103(a) rejection is traversed for at least the following reasons.

The references do not disclose or suggest an injection apparatus including a threaded segment having a plurality of threads having a pitch

As an initial matter, the combination of references cited in the § 103 rejection of the claims is improper because the references do not disclose or suggest an injection apparatus that includes a threaded component having a plurality of threads having a pitch. More specifically, each of amended independent claims 1 and 16 is directed to a device for connecting an injection needle to an injection apparatus “comprising a threaded segment having a plurality of threads having a pitch,” and none of the cited references discloses or suggests a device for joining to a threaded segment of an injection apparatus as claimed.

One skilled in the art viewing the specification as a whole will appreciate that the threaded segment of the injection device, as claimed, encircles the injection apparatus component for several revolutions. For example, the specification of the instant application illustrates several threaded segments having a thread 5 that encircles the injection device by at least six revolutions having varying pitches. See, e.g., Figures 1a, 1b, 2a, 2b, 2c and 2d.

None of Ashkenaz, Azzolini, Uchida, Aoki or Lynn discloses or suggests a device for connecting to an injection apparatus having a threaded segment as claimed. Rather, each reference discloses needle connectors for joining with an annular rim or bead of a device. See e.g., *Ashkenaz* at column 2, lines 37-46 (disclosing a bead-like fillet 19 shown at Figure 2); *Azzolini* at column 2, lines 40-42 (disclosing a rim 2a shown at Figure 2); *Uchida*, column 4, lines 16-22 (disclosing an opening 11 with a rim shown at Figure 1); *Aoki*, column 3, lines 45-55 (disclosing opening 17 of vial 3 formed as a rim shown at Figure 11); and *Lynn*, at column 4, lines 30-32 (disclosing conduit 4 having a conventional junction terminal 8 formed as a bead shown at Figures 9-13). Such a rim or bead is annular, encircles the device by a single

revolution, and clearly is not a threaded segment as claimed. Thus, the non-threaded devices of the cited references fundamentally differ from the claimed fixing apparatus and, in fact, teach away from it.

While claims are to be given their broadest reasonable interpretation, this interpretation must be consistent with the specification. *MPEP* 2111. One skilled in the art viewing the claims in view of the specification of the instant application will appreciate that “a threaded segment having a plurality of threads having a pitch” fundamentally differs from an annular rim or bead. Due to the references’ fundamental disclosure and teaching deficiencies with respect to the fixing device of amended independent claims 1 and 16, the rejection of the claims over the asserted Askenaz/Azzolini or Uchida or Aoki or Lynn combination is improper.

The cited references do not address the problem solved by the invention

Because none of the references discloses a needle connector for joining with an injection device comprising a threaded segment having a plurality of threads having a pitch, none of the cited references addresses the problem solved by the present invention. Specifically, the instant application explains:

The caps 1 each have a lower, open end and an upper, closed end which holds the needle 2 perpendicular and in the middle. In some embodiments, the caps 1 comprise a continuous single wall defining a generally central, hollow cavity. Spring elements 3 are arranged like bending beams on the inner surface area of the cap 1, and a cam 4 is situated in the middle of each spring element. *If the cap 1 is then turned over a thread 5, then in the existing device (FIG. 1a), the cams 4 engage with the flight 6 of the thread 5. If the positioning of the cams 4 is not adapted to the pitch of the flight 6, then the cap 1 disadvantageously tilts out of the perpendicular and/or the needle 2 is no longer parallel to the rotational axis 7 of the thread 5. Specification, page 7, lines 14-23 (emphasis added).*

In view of this problem, the instant application continues:

In the device in accordance with the present invention (FIG. 1b), the cams 4 are analogously attached on spring elements, but do not--as opposed to the existing cams 4--have a simple end tapering towards the thread 5. Due to a notch 8 running horizontally to the surface area of the cap 1, this end has two tips 9 which each act perpendicularly into the flight 6. The distance between the tips 9 of a cam 4 is at least the height of the flight 6, providing at least three points of contact between the fixing device or cap 1 and the thread 5, wherein said points of contact

are not in the same plane. The needle 2 is thus held securely, without tilting out of the perpendicular or rotational axis 7 of the thread 5. *Specification*, page 7, line 24 to page 8, line 3.

Accordingly, independent claims 1 and 16 have been amended to recite:

1. A fixing device for injection needles, for pushing onto an injection apparatus comprising a threaded segment having a plurality of threads having a pitch, wherein said fixing device is formed as a cap comprising an open lower end and a closed upper end which holds a needle perpendicularly in the middle, and a surface area of the fixing device comprises at least three spring elements fixedly connected to the cap so that the fixing device is at least slightly spring-elastic in its circumference, the spring elements each comprising a bending beam and a notched cam, each bending beam comprising a spring-elastic beam with a first end joined to the upper end of the cap and a second end joined to the lower end of the cap, and each notched cam comprising a surface substantially parallel to the surface area and tips and being fixed to a center-point of the bending beam, wherein when said fixing device is positioned on the threaded segment of the injection apparatus, the bending beams of the at least three spring elements elastically deform such that the notched cams are directed to said threaded segment and at least one of the tips of at least two of said notched cams perpendicularly engage with and provide at least three points of contact with the threaded segment.

16. A device for connecting an injection needle to an injection apparatus comprising a threaded segment having a plurality of threads having a pitch, the device comprising spring elements, said spring elements each comprising a bending beam and a notched cam to provide tips, the bending beam comprising a spring-elastic beam with a first end joined to an upper end of the device and a second end joined to a lower end of the device, the tips joined to a central portion of the bending beams and providing a plurality of possible points of contact between the device and the injection apparatus in at least two planes, and wherein when said device is positioned on the injection apparatus, the points of contact of the tips engage with the threaded segment generally perpendicularly and spring forces of the bending beams act generally perpendicularly on the threaded segment by way of the tips such that at least three points of contact are provided between the tips and the threaded segment of the injection apparatus.

The cited references do not disclose or suggest the spring elements as claimed

Amended independent claim 1 recites, in part: "spring elements each comprising a bending beam and a notched cam, each bending beam comprising a spring-elastic beam with a first end joined to the upper end of the cap and a second end joined to the lower end of the cap." Amended independent claim 16 recites, in part: "spring elements each comprising a bending

beam and a notched cam to provide tips, the bending beam comprising a spring-elastic beam with a first end joined to an upper end of the device and a second end joined to a lower end of the device.”

Ashkenaz, Azzolini, Uchida, Aoki and Lynn do not disclose or suggest the bending beams of the spring elements, each of which are joined to an upper and lower end of the cap or device. Rather, in Ashkenaz at figure 5, the longitudinal slots 33 simply result in the skirt 125 terminating in a free end. In Azzolini at figure 1, posts 11 terminate in a free end. In Uchida at figures 3 and 7, the legs 7 with the curved projections 8 terminate in a free end. In Aoki at figures 9-14, the pressing portion 56 terminates in a free end. In Lynn at figure 4, the fingers 32 and 34 terminate in a free terminal end. Because the cited references each disclose needle connectors that terminate in a free terminal end, the references, viewed alone or in combination, do not disclose or suggest the spring elements each with a bending beam joined to an upper and lower end as claimed.

The cited references do not disclose or suggest the function of the tips to provide at least three points of contacts by the notched cams of the spring elements as claimed

Amended independent claim 1 recites, in part: “when said fixing device is positioned on the threaded segment of the injection apparatus, the bending beams of the at least three spring elements elastically deform such that the notched cams are directed to said threaded segment and at least one of the tips of at least two of said notched cams perpendicularly engage with and provide at least three points of contact with the threaded segment.” Amended independent claim 16 recites, in part: “when said device is positioned on the injection apparatus, the points of contact of the tips engage with the threaded segment generally perpendicularly and spring forces of the bending beams act generally perpendicularly on the threaded segment by way of the tips such that at least three points of contact are provided between the tips and the threaded segment of the injection apparatus.”

None of the cited references disclose or suggest a threaded injection apparatus with a “threaded segment having a plurality of threads having a pitch,” the spring elements with the “bending beams” or tips providing at least three points of contact with the threaded segment.

The cited references do not disclose the function of the tips acting perpendicularly on the threaded segment as claimed

The claimed relationship and function of the tips to “perpendicularly engage” with the threaded segment (amended independent claim 1) and to “act generally perpendicularly on the threaded segment” (amended independent claim 16) is not disclosed or suggested by the cited references.

Conclusion

In view of the fundamental disclosure and teaching differences between the cited references and the claimed injection apparatus with the threaded segment, due to the fact that none of the cited references addresses the problem solved by the present invention and because the cited references do not disclose or suggest the structure or the function of the fixing device and injection device as claimed in amended independent claims 1 and 16, the asserted combination of the cited references does not provide a proper basis for the § 103 rejection.

Claims 2-6, 7-15, 18-19, and 22-25 depend directly or indirectly from amended independent claims 1 and 16 and are patentable for at least the reasons set forth above with respect to claims 1 and 16, further in view of their additional recitations.

No additional fees should be due in connection with this paper, but the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and

allowance are respectfully requested.

Respectfully submitted,

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